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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,319

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Paul D. Wightman

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EXAMINER

BERRIOS, JENNIFER A

ART UNIT

PAPER NUMBER

1619

NOTIFICATION DATE

DELIVERY MODE

09/15/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/821,319	<b>Applicant(s)</b> WIGHTMAN ET AL.	
	<b>Examiner</b> Jennifer A. Berrios	<b>Art Unit</b> 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2009 and 6/13/2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 26-43 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 26-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This office action is in response to the replies filed 6/13/2009 and 4/9/2009, wherein claims 1-16, 19-21 and 26-43 are currently pending. Claims 17-18 are withdrawn or cancelled, and claims 22-25 and 44-60 have been cancelled.

It is noted applicants have indicated claims 17 and 18 as “withdrawn” using the “withdrawn” status identifier. However, the text of the said claims 17 and 18 are deleted, which is not in compliant with the rule. (See MPEP 714 II). Applicants are requested to clarify the status of the said claims in response to the instant Office action.

### ***Terminal Disclaimer***

The terminal disclaimers filed on 7/9/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Applications 10/821335 and 11/360071 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Maintained Rejections***

Examiner would like to point out that the Provisional Double patenting rejection of instant claims 1-3, 5-7, 10, 14-16, 19-25, 31-33, 37 and 42-43 over claims 1, 2 and 71 of Application 10/640,904 has been modified as Application 10/640,904 was issued as a

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patent (US 7,427,629) after the mailing of the office action on 3/13/2008. No new references were added.

### ***Claim Objections***

1. Claim 1 is objected to because of the following informalities: The word "response" in the claim as an extra R "Response". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 and 19-21 and 26-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over CARUSO et al. (US 6,479,146 see PTO-1449) in view of HEMMI et al. (Nature Immunology, 2002 see PTO-1449) and in view of HAINFELD et al. (US 5,521,289 see PTO-892)

CARURO teaches a process for preparing particles, nanoparticles and colloidal particles and shells that are bound to various inorganic and organic structures. CARURO teaches nanoparticles suitable for immunological detection methods, drug delivery systems for transport of active agents, microscopy and other areas of medicine, pharmaceuticals, magnetics and sensing methods using biologicals such as nucleic acids, proteins and immuno reactive proteins. See e.g. col 5 lines 38-46 and 63-66, col 4 lines 27-29; instant claims 1 and 2. The reference teaches that the particles if inorganic are gold, magnetic, ceramic, polymers or oxides. See e.g. col 5 lines 65-67, col 6 lines 56-62, Example 5; instant claims 1-11, 26-30 and 34-40. The permeability and density of a shell comprising colloidal particles can be controlled. See e.g. col 6 lines 15-26; instant claims 5, 12, 13 and 34. The particles size is 640 nm with a range from 15um or less, preferably 100nm to 1um. See e.g. Example 5 and col 6 lines 31-33; instant claims 14, 15, 16, 37, 41 and 43. Pharmaceutical drugs and biologically

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active compounds are attached to the particle. See e.g. col 6 lines 39-40 and Example 4; instant claim 31.

CARUSO does not explicitly teach the specific species of IRMs from the instant invention or that the attachment to the particulate or solid support is a covalent bond.

HEMMI teaches an immune response modifier comprising imidazoquinoline and derivatives that functions through the activation of the TLR7. HEMMI further teaches that Toll-like receptors (TLRs) play a critical role in innate immune responses in mammals. For example TLR6 can associate with TLR2 and recognize peptidoglycan and lipopeptides. They recognize all microbial components contained in vaccine adjuvants, which indicate that TLRs act as adjuvant receptors to control innate and adaptive immune responses. See e.g. page 196 and page 197 Results and page 199; instant claims 1, 19-25, 34, 37, 39 and 42.

HAINFELD teaches a core of solid metal atoms bonded to organic molecules. HAINFELD teaches the core is colloidal surrounded by a shell of organic groups which are suitable for covalent linking to other molecules or compounds, e.g. antibodies, antibody fragments, peptides, drugs, antigens, DNA, RNA, or other biological molecules, which read on DNA vaccine or vaccines in general, as antibodies and DNA can be used as a vaccine. See e.g. col 2 lines 43-56; instant claims 2, 3, 4, 10, 11, 26-30, 32-33 and 36-42.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a composition comprising an IRM compound, for the benefit taught by HEMMI, on a particulate support material comprising at least one

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metal, as taught by CURUSO in view of HEMMI and in view of HAINFELD. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single composition because CURUSO and HAINFELD teach the support complex e.g. gold and HEMMI teaches the IRMs and because CURUSO and HAINFELD suggest the attachment, particularly a covalent attachment of drugs, DNA and other pharmaceutical and medical compounds to the support. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

### ***Response to Arguments***

Applicant argues that neither the 3 references alone or in combination fail to enable how one would attach an IRM compound claimed to a metal-containing particle and whether the IRM compound would remain biologically active after being attached. This is not found persuasive because examiner has not provided any factual evidence demonstrating that one of skill in the art would not the knowledge necessary to attach the IRM compounds and applicant states of Pg 26, lines 5-6 of the instant specification that "IRM compounds may be covalently bonded to a particulate support material by any methods known in the art." With regards to the activity of the TLR receptors, if the IRM-support complex of the instant claims is taught by the combined references of CARUSO/HEMI/HAINFELD, its expected that IRM and the IRM support complexes would have or retain the same properties. *It is noted that In re Best (195 USPQ 430)*

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*and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).*

Applicant further argues that while CARUSO disclosed various nanoparticles with drugs, it appears that the encapsulation of the drug is within hollow shells, not adhering the drug "on" the particles as required by the instant claims. This is not persuasive because the instant claims read "IRM on/attached to a particulate support material." The instant specification states on Pg 10, lines 10-11: "The terms "coupled," "conjugated," "bonded," or "immobilized" may be used herein to represent "attached." Examiner would like to point out that conjugated is defined as "united with another compound." As such regardless of the fact that the drug is encapsulated within or on the surface of the hollow shell, they are still two compounds united or bonded together, as such the limitations of the instant claims are met.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent



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and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-7, 10, 14-16, 19-25, 31-33, 37 and 42-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 18-24 and 32 of copending Application No. 10/821330. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because they comprise an IRM attached to a support material.

US 10/821335 teaches an IRM support complex comprising an IRM compound covalently bonded to a macromolecular support material. The macromolecular support can be a metal, see '335 spec page 22 line 4.

All these above applications either have an IRM compound on a particular support with a metal or it would have been obvious to a person of skill in the art at the time of the invention to be motivated to use a metal in the support material as suggested by HAINFELD and CURUSO.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-7, 10, 14-16, 19-25, 31-33, 37 and 42-43 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,427,629 in view of HAINFEL.

US Patent 7,427,629 teaches the IRM is attached to a solid support. While the application does not teach the support comprises at least one metal, the teachings of HAINFELD would have motivated one skilled in the art at the time of the invention to use a support with at least one metal for the delivery of the IRM.

***Response to Amendment***

Applicant argues that neither of the applications disclose an IRM attached to a support comprising a metal and HEINFELD does not suggest attaching to a metal-containing support material compounds like IRM's or that the IRM compounds would remain active, nor does HEINFELD provide any teaching as to enable one of skill in the art to be able to attach the IRMs to the particulate-support.

This is not found persuasive because applicant has not provided any factual evidence demonstrating that one of skill in the art would not have the knowledge necessary to attach the IRM compounds and applicant states of Pg 26, lines 5-6 of the instant specification that "IRM compounds may be covalently bonded to a particulate support material by any methods known in the art." With regards to the activity of the TLR receptors, if the IRM-support complex of the is taught by the combined references of HAINFELD and the instant claims, its expected that IRM and the IRM support complexes would have or retain the same properties. *It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).*

Applicant argues that HEINFELD does not suggest attaching IRM material to metal particulate supports, this is not found persuasive because HEINFELD teaches

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attaching a variety of biomolecules, such as antibodies, DNA, RNA, etc and IRM are biomolecules, as such on of skill in the art would have been motivated to substitute one equivalent (biomolecule) for another.

### ***Conclusion***

No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Berríos whose telephone number is (571)270-7679. The examiner can normally be reached on Monday-Thursday: 7:00am-4:00pm (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JB

*/SUE LIU/*

*Primary Examiner, Art Unit 1639*